

Summary: Comparative Rodenticide Assessment

October 8, 2002

Background

When the rodenticide cluster and zinc phosphide REDs were issued in 1998, EPA noted that recent information had come to the Agency's attention regarding potential adverse effects to birds and non-target mammals. The 1998 Rodenticide Cluster RED stated that EPA planned to further evaluate these potential risks to determine if additional risk mitigation is indicated prior to concluding that uses are eligible for reregistration.

The Rodenticide Registrants Task Force (RRTF) formed in late 1998 following the release of the draft Rodenticide Cluster RED. Since 1999, the RRTF has participated in many meetings with the Agency to address issues of shared concern regarding the evaluation and use of rodenticides.

In October, 1999, EPA held an all-day public meeting during which EPA presented a comparative approach to ecological assessment for rodenticides. States, industry, and environmental groups also presented their perspectives on ecological risk, and public comments were requested. EPA decided to use a public participation process to ensure broad stakeholder input on the risk assessment and any resulting mitigation options.

Status

In November, 2001, EPA completed a preliminary ecological risk assessment, "*Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals*," and initiated the first phase of the public participation process: error-only review of the assessment by rodenticide registrants.

The central purpose of the assessment is to evaluate each of the nine rodenticides and rank them in terms of potential primary, secondary, and overall risk to non-targets to determine if risk reduction measures are indicated.* Since September of 2001, the Agency has agreed to meet with the RRTF on five separate occasions to listen to and discuss their concerns with the preliminary assessment. (Materials from those meeting are available in the public docket.) The RRTF, in their error comments and during meetings with EPA, has presented five general concerns with the preliminary assessment:

- The document is a hazard assessment and not a risk assessment.
- The decision table analysis methodology provides only a ranking of relative hazard and thus cannot be used to evaluate true hazard or true risk.
- The document contains serious technical errors that, if corrected, should materially change the risk conclusions.
- The document does not adequately consider formulated products or label use patterns that should be key elements in any risk assessment. And
- Liver residues are considered adverse effects in the document, but low-level residues are not definitive evidence of a causative agent (only markers of exposure) and should be carefully interpreted.

Based on these concerns, the RRTF has stated that the assessment should not be published for public comment in its current form. EPA notes that this is the preliminary comparative assessment which may be refined and/or revised significantly based on comments or additional data.

EPA has made several revisions to the assessment based on comments and has prepared responses to the written comments submitted by the RRTF and each of the individual registrants during the error-only comment period. EPA notes that many of the comments relate to general risk assessment methodology, science policy, or interpretation of the data which are generally not addressed during error-only review. However, EFED has made the following revisions:

- Edited the risk assessment and inserted some clarifying paragraphs on framing the problem.
- Pointed out limitations with our secondary exposure assessment.
- Pointed out uncertainties. And
- Deleted phrases that had any suggestion of risk mitigation.

After considering multiple comments from the RRTF, EPA believes that all comments and concerns have been adequately discussed and incorporated (where applicable) into the current risk assessment, and it is appropriate and important to now obtain comment from all stakeholders and the scientific community on the assessment. Therefore, EPA seeks input and feedback on all aspects of the assessment including the RRTF's issues noted above.

* The methodology used in this assessment is similar to that used in the Agency's "Comparative Analysis of Acute Risk From Granular Pesticides" and "A Comparative Analysis of Ecological Risks From Pesticides and Their Use: Background, Methodology, Case Study"; both were reviewed by a FIFRA SAP. Concerning the latter analysis, the Panel noted that many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel also made a number of helpful suggestions to improve the utility of the method presented for use in comparative analyses of ecological risk from pesticides. However, there were two recommendations that the panel thought critical for valid results which included: risk quotients should never be combined; and, a sensitivity analysis should always be included. Following this advice, no risk quotients or indices have been added together for this analysis, and a sensitivity analysis has been included.